Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 11-14-2014.

Submission # 8

As of 10-29-2014, this request was received. However, it was received outside of the twenty day approval period. This request will not be reviewed or approved for oral testimony.

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

October 29, 2014

Tami Eide, PharmD
3232 Elder Street
Boise, ID 83705

Dear Dr. Eide:

Thank you for your interest in APTIOM® (eslicarbazepine acetate) Tablets. The enclosed information is in response to your request regarding information for your November 2014 P&T Committee meeting. Your request was forwarded by your Health Economics and Outcomes Research (HEOR) Liaison, Kim Laubmeier, regarding:

• Aptiom® (eslicarbazepine acetate) Tablets – P&T Committee Meeting – Oral Testimony

The enclosed information is supplied as a professional courtesy in response to your inquiry. It is intended to provide pertinent data that will assist you in forming your own conclusions and making your own decisions. This information is not intended to advocate any indication, dosage, or other claim that is not covered in the enclosed package insert.

Should you have any questions or need additional information, please contact Sunovion Medical Information directly at 1-800-739-0565.

Thank you again for your interest in APTIOM.

Sincerely,

Hiren Patel, Pharm.D.
Senior Manager, Medical Information

CC: David Blum, MD
Executive Medical Director, Clinical Development & Medical Affairs
Enclosure: Package Insert-APTIOM® (eslicarbazepine acetate) Tablets
2014-007610

Aptiom® (eslicarbazepine acetate) – P&T Committee Meeting – Oral Testimony

Thank you for your interest in Aptiom Tablets. Enclosed is the oral testimony provided in response to your request for information for your November 2014 P&T Committee Meeting.

For U.S. Healthcare Professional Use Only. This information is provided as a professional courtesy in response to your unsolicited request for information and may contain information that is not part of the FDA approved labeling. It is intended to provide pertinent data that will assist you in forming your own conclusions and making your own decisions. This information is not intended to advocate any indication, dosage, or other use that is not covered in the Full Prescribing Information. Please see the enclosed Full Prescribing Information for important safety information.[1] Do Not Copy or Distribute. For Informational Purposes Only.

INDICATION AND USAGE

APTIOM (eslicarbazepine acetate) is indicated as adjunctive treatment of partial-onset seizures.

DOSAGE AND ADMINISTRATION

APTIOM can be administered as whole or crushed tablets, taken with or without food.

Start treatment at 400 mg once daily. After one week, increase dosage to 800 mg once daily, which is the recommended maintenance dosage. Some patients may benefit from the maximum recommended maintenance dosage of 1200 mg once daily, although this dosage is associated with an increase in adverse reactions. A maximum dose of 1200 mg daily should only be initiated after the patient has tolerated 800 mg daily for at least a week. For some patients, treatment may be initiated at 800 mg once daily if the need for additional seizure reduction outweighs an increased risk of adverse reactions during initiation.

Dose Modifications

Use with Other AEDs:

- APTIOM should not be taken as an adjunctive therapy with oxcarbazepine.
- Some adverse reactions occur more frequently when patients take APTIOM with carbamazepine. Carbamazepine reduces the plasma concentration of eslicarbazepine; when APTIOM and carbamazepine are taken concomitantly, the dose of APTIOM or carbamazepine may need to be adjusted based on efficacy and tolerability.
- For patients taking other enzyme-inducing antiepileptic drugs (AEDs) (i.e., phenobarbital, phenytoin, and primidone), higher doses of APTIOM may be needed.

Patients with Renal Impairment: A dose reduction is recommended in patients with moderate and severe renal impairment (i.e., creatinine clearance <50 mL/min). Start treatment at 200 mg once daily. After two weeks, increase dosage to 400 mg once daily, which is the recommended maintenance dosage. Some patients may benefit from the maximum recommended maintenance dosage of 600 mg once daily.

Patients with Hepatic Impairment: Dose adjustments are not required in patients with mild to moderate hepatic impairment. Use of APTIOM in patients with severe hepatic impairment has not been studied, and use in these patients is not recommended.

When discontinuing APTIOM, reduce the dosage gradually and avoid abrupt discontinuation in order to minimize the risk of increased seizure frequency and status epilepticus.

REFERENCE

1. Aptiom® (eslicarbazepine acetate) tablets [package insert]. Marlborough, Mass: Sunovion Pharmaceuticals Inc.

ENCLOSURE

1. Aptiom® (eslicarbazepine acetate) tablets [package insert]. Marlborough, Mass: Sunovion Pharmaceuticals Inc.

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ID Medicaid 3-min Testimony (Verbal Script)

November 14, 2014

Good morning, my name is Kim Laubmeier and I am Director of Health Economics and Outcomes Research with Sunovion Pharmaceuticals Inc. Thank you for the opportunity to present to you today regarding the clinical and pharmacoeconomic profile of eslicarbazepine acetate, commercially known as APTIOM®. APTIOM is FDA-approved for use as adjunctive treatment of partial-onset seizures in adults. APTIOM is not a controlled substance, and may be taken whole or crushed, with or without food.

In the clinical trials that led to the FDA approval of APTIOM, patients had a median duration of epilepsy of 19 years, with poorly controlled seizures despite 1-3 epilepsy medications, and were experiencing a median of 8 seizures per month (Aptiom PI). APTIOM demonstrated a statistically significant reduction in standardized seizure frequency; the secondary endpoint of at least 50% reduction in seizure frequency showed a response in as many as 31-43% of refractory POS patients across the 800mg/day and 1200mg/day strengths, respectively (April 2014 AMCP Dossier). APTIOM does not have a boxed warning; however, it does have the following important warnings and precautions: suicidal behavior and ideation, withdrawal seizures - both of which are class effects - and serious dermatologic reactions, drug reaction with eosinophilia and systemic symptoms, anaphylactic reactions and angioedema, hyponatremia, neurological adverse reactions, and drug induced liver injury. The most common adverse reactions in patients taking APTIOM at these doses (4% or greater) were dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. The most common psychiatric side effect was depression in 3% of patients who received APTIOM 1200 mg, compared to 1% for patients on placebo. I refer you to the full prescribing information for a complete list of warnings, precautions and adverse events.

While there are no direct head-to-head comparisons between the different AEDs, a cost effectiveness model based on a network meta-analysis of phase III randomized controlled trials of branded AEDs for the treatment of partial onset seizures in adults showed APTIOM to be cost effective on a cost per seizure avoided basis and on cost per response-month basis, with efficacy comparable to Keppra XR, and superior to Vimpat. Furthermore, budget impact modeling suggests a net neutral impact on the formulary budget by addition of APTIOM (data on file).

In closing, APTIOM is a once-daily treatment option for adjunctive use in adult patients with POS. APTIOM has demonstrated efficacy in refractory POS patients, which is important in this difficult to treat patient population. I respectfully ask that unrestricted access to APTIOM be provided to the Medicaid beneficiaries of Idaho.

This concludes my presentation.